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UNITED STATES DEPARTMENT OF COMMERCE
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Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,670,444, was filed on December 3, 1996, under 35 U.S.C. § 156. U.S. Patent No. 4,670,444 issued on June 2, 1987.

The assistance of your Office is requested in confirming that the product identified in the application, BAYTRIL®, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156 if the product is a new animal drug which has received permission for the commercial marketing or use in non-food-producing animals and in food-producing animals, and the permission for commercial marketing or use of the product after the regulatory review period for use in food-producing animals is the first permitted commercial marketing or use of the product for administration to a food-producing animal. See 35 U.S.C. § 156(a)(5)(A).

Inquiries regarding this communication should be directed to Karin Tyson at (703) 306-3159.



Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Project

cc: Kurt G. Briscoe
Sprung Horn Kramer & Woods
660 White Plains Road
Tarrytown, New York 10591-5144

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